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DOC

(54) Pharmaceutical compositions on egg shell basis and their preparation and use.

(57) The invention relates to a pharmaceutical composition on the basis of purified, powdered and sterilized egg shell material and a method for their preparation. The pharmaceutical compositions of the invention may be advantageously utilized for the treatment of mineral deficiency diseases, particularly of bone and/or joint tissues. These compositions are optimally tolerated and utilized by the treated organism.

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Pharmaceutical compositions on egg shell basis and their preparation and use

The invention relates to pharmaceutical compositions on the basis of egg shells, particularly chicken egg shells, methods for their preparation, and their medical and pharmaceutical use.

The main elements contained in the compounds of egg shells are calcium, phosphorus, magnesium and a number of trace elements, in biogenous bonding. In addition thereto, egg shells contain constituents which are not comprised in present pharmaceutical compositions for the treatment of mineral deficiency diseases, etc.

At present, mostly inorganic raw materials are used for the preparation of different medicaments in this respect in the pharmaceutical industry. Medicaments prepared from inorganic raw materials, however, either do not comprise certain elements or contain these elements only in a form which does not enable their full physiological utilization. Actually, there is no really effective medicament available which could be applied for the treatment of certain diseases, particularly of osteoporosis, coxarthrosis and the like, which have been prepared on the basis of organically/biologically transformed and synthetized mineral compounds and of trace elements with proteinaceous bonding.

It is the object of the present invention to provide novel pharmaceutical compositions on the basis of egg shells, particularly chicken egg shells, which can be effectivly utilized for medical purposes for the treatment of certain diseases, particularly mineral deficiency diseases, in particular with respect to living tissues, which can be fully utilized by the treated organism and also comprise certain elements in proteinaceous bonding, and to provide a method for their preparation and their pharmaceutical use.

The above object is achieved according to the claims. The dependent claims relate to preferred embodiments.

The pharmaceutical compositions according to the present invention may be obtained by the following process:

(A) emptying eggs, preferably chicken eggs,

(B) removing residues of egg yolk and white of egg, ballast constituents, contaminants and the membrane sticking to the interior egg shell surface, and purifying the egg shells,

(C) drying the egg shells with hot air,

(D) crushing and grinding the egg shells to a powder having a particle size of ≤ 150 µm, and preferably of 10 to 80 µm,

and

(E) sterilizing the egg shell powder at a temperature sufficiently high to devitalize pathogenous and conditionally pathogenous microorganisms.

According to a preferred embodiment, removal of residues of egg yolk and white of egg and other constituents and contaminants including the membranes sticking to the interior surface of the egg shells is carried out by mechanical treatment and preferably by centrifugation; the subsequent purification is preferably carried out by washing with pure water and removing the water in step B, preferably by centrifugation.

According to another preferred embodiment, the drying of the egg shell material in step C is carried out with hot air of a temperature of ≤ 150 and preferably of 60 to 120 °C.

In accordance with another preferred embodiment, the crushed and ground egg shell material is sieved for obtaining particles having a diameter within a predetermined particle size range.

The pharmaceutical compositions according to the present invention are capable to fully balance deficient biogenous mineral compounds and trace elements in the treatment of a number of diseases, particularly deficiency diseases, such as osteopathia and kondropathia, and other diseases of bones and joints where remineralization is required, as osteoporosis, coxarthrosis etc., and where an increased speed of callus formation is required. Actually used preparations for the treatment of similiar diseases are based merely on inorganic compounds and thus are generally only little effective, particularly for geriatric purposes whereby there is also a considerable risk of lethal effects in gerontological applications.

So far egg shells have already been used for curing certain diseases, their application has been based rather on intuition without provision of a compound having stable, standardized properties, and without determination of their specific effectiveness and activity based on objective biological knowledge and pharmaceutical methods.

The speed and efficiency of metabolization of the pharmaceutical compositions according to the present invention can be checked by pharmacokinetic methods and by X-ray and particularly densitometric investigations of the conditions of the whole skeleton or of local areas, e.g. fractures, and of changes of the

conditions of joints, spine and/or different bone tissues, in addition to the determination of a subjective improvement of the health condition of the patients.

The pharmaceutical compositions according to the present invention proved particularly effective for geriatry where currently used medicaments have not been effective or exhibited unfavourable side effects, or have not been properly tolerated by the body.

The pharmaceutical compositions according to the invention may be used in the form of the powder as obtained according to the above mentioned preparation method, whereby the application of the product in the form of a powder is most effective.

Alternatively, the pharmaceutical compositions may be transformed into other galenic forms, e.g. by introducing other active ingredients and/or usual carriers, additives and/or excipients.

The method for preparing the compositions according to the invention from egg shells will be described in the following with more details.

After removal of egg yolk and white from eggs, the egg shells are first mechanically treated, preferably in a centrifugal separator, in order to remove any remaining egg yolk or white of egg; the centrifuged shells are than washed in water to remove residues and the membrane film sticking to the internal surface of the egg shells and for removing other contaminants; the material is subsequently rinsed with pure water whereafter the water is removed, advantageously by a centrifugal separator. The obtained product is then dried with hot air of a temperature of up to 150 °C, advantageously of a temperature of 60 to 120 °C, with following crushing and grinding to a fine powder of a particle size of up to 150 µm and advantageously between 10 and 80 µm. The product may then be sieved and is subsequently sterilized in order to devitalize pathagenous and conditionally pathogenous microorganisms. This sterilization should be carried out for about 1 h at a temperature of about 120 °C. The obtained final product may then be checked for possible traces of microorganisms.

The thus obtained powder comprises substantially the following biologically bonded elements:

Calcium	30,0 to 40,0 g/100 g of powder
magnesium	0,35 to 0,5 g/100 g,
phosphorus	about 0,08 g/100g,
carbonates	46,0 to 60,0 g/100 g,
	and
nitrogen	0,5 to 0,6 g/100 g,

and other biogenous elements, all in biological bonding.

The pharmaceutical compositions of the present invention may be advantageously administered per os. Nevertheless, also other usual galenic forms may be used for administration.

The pharmaceutical compositions according to the invention can be advantageously utilized in medical therapy, particularly in pediatry, traumatology, geriatry, orthopedy, stomatology, puerperium, oncology and pneumopathy.

Claims

1. Pharmaceutical compositions on the basis of egg shells, obtainable by

(A) emptying eggs, preferably chicken eggs,

(B) removing residues of egg yolk and white of egg, ballast constituents, contaminants and the membrane sticking to the interior egg shell surface, and purifying the egg shells,

(C) drying the egg shells with hot air,

(D) crushing and grinding the egg shells to a powder having a particle size of ≤ 150 µm, and preferably of 10 to 80 µm,

and

(E) sterilizing the egg shell powder at a temperature sufficiently high to devitalize pathogenous and conditionally pathogenous microorganisms.

2. Pharmaceutical compositions according to claim 1, obtainable by mechanical treatment, preferably by centrifugation, subsequent washing with pure water, and removing the water, preferably by centrifugation, in step B.

3. Pharmaceutical compositions according to claim 1 or 2, obtainable by drying the egg shells in step C with hot air of a temperature of ≤ 150 °C and preferably of 60 to 120 °C.

4. Pharmaceutical compositions according to one of claims 1 to 3, obtainable by sieving the ground egg shell material in step D.

5. Pharmaceutical compositions according to one of claims 1 to 6, comprising, in addition to trace elements and other biogenous elements,

calcium	30 to 40 g/100 g of powder,
magnesium	0,35 to 0,5 g/100 g,
phosphorus	about 0,08 g/100 g,
carbonates	46,0 to 60,0 g/100 g,
	and
nitrogen	0,5 to 0,6 g/100 g,

in biological bonding.

6. A method for preparing the pharmaceutical compositions according to one of claims 1 to 5, characterized by

(A) emptying eggs, preferably chicken eggs,

(B) removing residues of egg yolk and white of egg, ballast constituents, contaminants and the membrane sticking to the interior egg shell surface, and purifying the egg shells,

(C) drying the egg shells with hot air,

(D) crushing and grinding the egg shells to a powder having a particle size of ≤ 150 µm, and preferably of 10 to 80 µm,

and

(E) sterilizing the egg shell powder at a temperature sufficiently high to devitalize pathogenous and conditionally pathogenous microorganisms.

7. The method according to claim 6, characterized by mechanical treatment, preferably by centrifuging, subsequent washing with pure water, and removing the water, preferably by centrifugation, in step B.

8. The method according to claim 6 or 7, characterized by drying the egg shells in step C with hot air of a temperature of ≤ 150 °C and preferably of 60 to 120 °C

9. The method according to one of claims 6 to 8, characterized by sieving the ground egg shell material in step D.

10. Use of the pharmaceutical compositions according to one of claims 1 to 5 for the galenic formulation of pharmaceutical compositions for the treatment of mineral deficiencies, particularly in joint and bone tissues and particularly of osteoporosis and coxarthrosis.

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EUROPEAN SEARCH REPORT

Application Number

EP 89 11 1364

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X	PATENT ABSTRACTS OF JAPAN, vol. 8, no. 260 (C-254)[169], 29th November 1984; & JP-A-59 137 415 (MINORU ONODA) 07-08-1984 * Abstract * ---	1-10	A 61 K 35/54
A	CHEMICAL ABSTRACTS, vol. 76, no. 20, 15th May 1972, page 324, abstract no. 117501z, Columbus, Ohio, US; & CZ-A-139 908 (J. SPINKA) 15-01-1971 ---		
A	US-A-3 558 771 (L.L. BALASSA) -----		

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 K

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	12-12-1989	ALVAREZ Y ALVAREZ C.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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E : earlier patent document, but published on, or after the filing date
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